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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,859	02/27/2004	Raman K. Bakshi	21291Y	6828

210 7590 11/22/2005

MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER

FREISTEIN, ANDREW B

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/788,859

Applicant(s)

BAKSHI ET AL.

Examiner

Andrew B. Freistein

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40, 47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 25-29 and 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 11, 14, 15, 30 and 38-40 is/are rejected.
- 7) ☒ Claim(s) 1-24, 30, 38-40, 47 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/27/04 & 8/3/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-40 and 47-48 are currently pending. Claims 41-46 were cancelled by amendment.

Priority

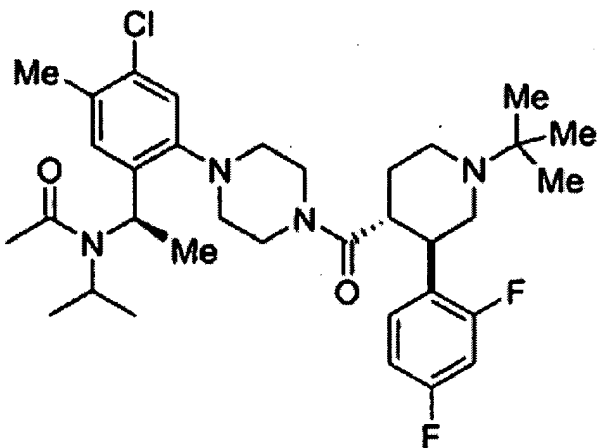
This application claims benefit of US Provisional Application Nos. 60/515,943, filed 10/30/2003 and 60/451,502, filed 03/03/2003.

Information Disclosure Statement

Applicant's information disclosure statements (IDSs), filed on April 27, 2004 and August 3, 2005, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Response to Restriction Requirement

Acknowledgement is made of Applicant's election (with traverse) of Group I,
Claims 1-24, 30 and 38-40, and the species



F, in a response filed 10/12/2005. Newly added claims 47-48 are joined as part of Group I. Claims 41-46 were cancelled by amendment and as a result Group IV has been cancelled.

The Examiner respectfully disagrees with the Applicant because the products of Inventions I-III differ materially in structure and element and from each other and are therefore capable of supporting their own patents. The invention groups I-III are related to a set of structurally diverse compounds, their methods of use, and pharmaceutical compositions with intended use. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The chemical structures claimed do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Due to the plethora of classes and subclasses in each of group, separate search considerations are involved, which would impose a serious burden on the Examiner.

Nevertheless, Examiner may reconsider to rejoin the method of use claims and the pharmaceutical composition claims commensurate in scope with the product claims when and if the case is found to be in condition for allowance provided those method of use claims and pharmaceutical composition claims are free of 35 U.S.C. § 112 first and second paragraph issues (including written description, reach-through claim language and/or scope of enablement issues).

Applicants reserve their right to file a divisional application on the non-elected subject matter.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

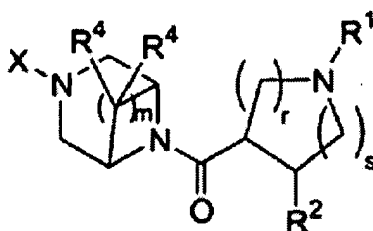
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-7, 11, 14, 15 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Levy et al., (US 2003/0153556).

Applicant claims "Acylated piperazine derivatives as melanocortin-4 receptor agonists.

Claim 1 of the instant application claims a compound of the formula (I),

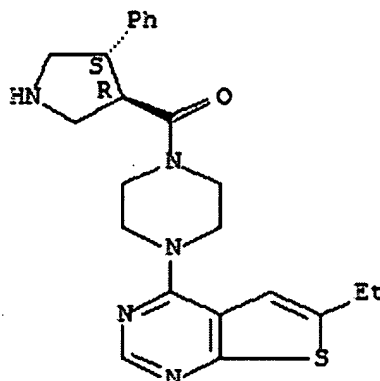


, wherein X is $(CH_2)_n$ -heteroaryl; R^1 is H; R^2 is phenyl; r is

1; s is 1; m is 0; and n is 0.

Claim 30 claims a pharmaceutical composition comprising a compound of claim

1.



Levy et al. disclose the compound:
p. 134, Ex. 434).

(see Levy et al.,

Levy et al. also disclose pharmaceutically acceptable salts, hydrates and isomers of the compound and pharmaceutical compositions comprising products thereof (see p.13, paragraphs [0074], [0075] and [0076] and p. 14, paragraphs [0078] and [0079]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

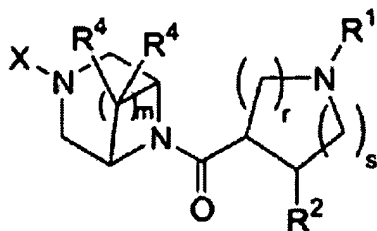
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al., (US 2003/0153556).

Applicant claims "Acylated piperazine derivatives as melanocortin-4 receptor agonists.

Claim 1 of the instant application claims a compound of the formula (I),



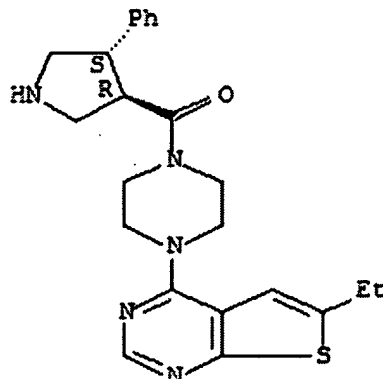
, wherein X is (CH₂)_n-heteroaryl; R¹ is H; R² is phenyl; r is 1; s is 1; m is 0; and n is 0.

Claims 38 claim the compound of claim 1 wherein the pharmaceutically acceptable salt is hydrochloride salt.

Claim 39 claims the compound of claim 1 wherein the pharmaceutically acceptable salt is trifluoroacetic acid salt.

Claim 40 claims the compound of claim 1 wherein the pharmaceutically acceptable salt is bis phosphate salt.

Determining the Scope and Content of the Prior Art



Levy et al. disclose the compound: (see Levy et al., p. 134, Ex. 434).

Levy et al. also disclose pharmaceutically acceptable salts, hydrates and isomers of the compound and pharmaceutical compositions comprising products thereof (see US 2003/0153556 p.13, paragraphs [0074], [0075] and [0076] and p. 14, paragraphs [0078] and [0079]).

Ascertaining the Differences Between the Instant Application and the Prior Art

The prior art discloses the compound, but does not disclose the specific salts claimed in the instant application bonded to the compound.

Finding Prima Facie Obviousness

One of ordinary skill in the art, a pharmaceutical chemist, would produce the most stable compounds for pharmaceutical use. The prior art claims the compound plus pharmaceutically acceptable salts, hydrates and isomers thereof. One of ordinary skill in the art would be motivated to produce the salts of the instant application by reading the disclosure found in the prior art.

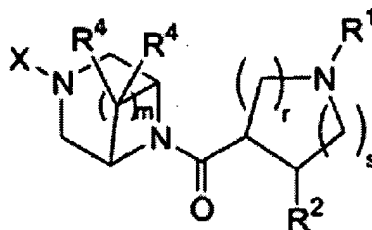
Status of the Claims

Claims 1-40 and 47-48 are currently pending in the instant application.

Claims 1-24, 30, 38-40, and 47-48 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



Compounds of the Formula (I),

, wherein:

X is as defined in claim 1;

R¹ is as defined in claim 1:

R² is phenyl or naphthyl, substituted or unsubstituted as defined in claim 1;

R³ is as defined in claim 1;

R⁵ is as defined in claim 1;

R⁶ is as defined in claim 1:

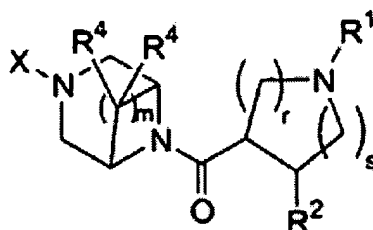
R^7 is as defined in claim 1:

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 R^8 is as defined in claim 1; R^9 is as defined in claim 1; r is 1 or 2; s is 1; m is 0; n is as defined in claim 1; and p is as defined in claim 1.

Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:



Compounds of the Formula (I),

, wherein:

 R^2 is heteroaryl; R^4 is as defined in claim 1; s is 0 or 2; and m is 1, 2, 3, or 4;

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 1-24, 30, 38-40, and 47-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups

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such as thiazolidine, piperazine, quinoline, thiophene, morpholine, oxazol, pyrimidine, pyrazine, pyran, etc. which are chemically recognized to differ in structure, function, and reactivity.

Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

Claim Objections

Claims 1, 3, 5, 14, 15, 16, and 17 are objected to as being drawn to non-elected subject matter.

Claims 2-15, 17-24, 30, 38-40, and 47-48 are objected to as being depended upon a rejected base claim.

Claim 16 is objected to, because it is an independent claim. Claim 16 should be amended to depend from claim 1 in order to avoid any future Obviousness-type Double Patenting rejections.

Telephone Inquiry

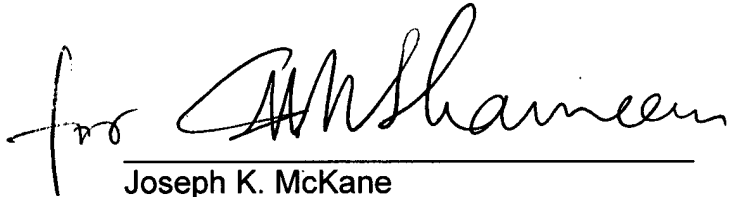
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein
Patent Examiner, AU 1626

for Joseph K. McKane

Joseph K. McKane
Supervisory Patent Examiner, AU 1626
Date: November 14, 2005